Section 5: 510(k) Summary

CONTACT INFORMATION

JAN - 3 2007

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COMPANY INFORMATION

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Telephone: (925) 460-6080
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DEVICE NAME

Sanarus V2 Treatment System

DEVICE DESCRIPTION

The V2 Treatment System consists of a control unit that controls one single-use, disposable V2 ICE Probe. The system utilizes a cryogen as a cooling agent and a resistance heater for thawing.

The V2 Console is a self-contained, mobile unit, which features an easy-to-use touch screen interface for complete control and monitoring of the cryoablation procedure. The touch screen allows users to select treatment modes and times and control the system and its cycles. The screen is mounted on the system and will tilt and swivel as needed. The Console operates off standard 120/240 VAC (60/50 Hz) power.

The V2 ICE Probe is a single use, disposable probe designed for use with the V2 Treatment System. The primary components of the V2 ICE Probes consist of a surgical stainless steel probe with an electrical warming component and an integrated T-Type Thermocouple for internal temperature feedback. The V2 Probe temperature is internally and continuously monitored by the V2 Console.

INDICATIONS FOR USE

Indications for Use: The device is indicated for use in general surgery, gynecology and oncology. The system is designed to destroy tissue by the application of extreme cold temperatures. In addition the system is intended for use in the following indications:

General Surgery

- Ablation of breast fibroadenoma
- Localization of breast lesions

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Sanarus Visica® Treatment System

SUBSTANTIAL EQUIVALENCE

The Sanarus V2 Treatment System is substantially equivalent to the Sanarus Visica Treatment System that was determined to be substantially equivalent on July18, 2006 (reference K061510).

The Sanarus V2 Treatment System has the same indications for use and technological characteristics as the predicate device. The patient contact components and component materials in both the new and predicate device are the same. The packaging materials, packaging configurations, sterilization methods and sterility assurance level are also equivalent.

Based on the indications for use, technological characteristics and performance testing results, the Sanarus V2 Treatment System does not raise significant new questions of safety and effectiveness.

PERFORMANCE TESTING SUMMARY

Performance testing confirms that the Sanarus V2 Treatment system meet its applicable specifications and performance standards and is substantially equivalent to the Sanarus Visica Treatment System predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sanarus Medical, Inc.
% Mr. Alan Marquardt
Vice President of Regulatory
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4696 Willow Road
Pleasanton, California 94588

JAN - 9 2007

Re: K062896
Trade/Device Name: Sanarus V2 Treatment System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: December 20, 2006
Received: December 21, 2006

Dear Mr. Marquardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number: K062896

Device Name: Sanarus V2 Treatment System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorat...
and Neurological Devices

510(k) Number K062896